PATENT COOPERATION TREATY

PCT/IB2006/052612

From the INTERNATIONAL BUREAU

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NOTIFICATION CONCERNING TRANSMITTAL OF COPY OF INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (CHAPTER I OF THE PATENT COOPERATION TREATY)
(PCT Rule 44bis.1(c))

To:

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Date of mailing *(day/month/year)*	
14 February 2008 (14.02.2008)	
Applicant's or agent's file reference 110/05400	**IMPORTANT NOTICE**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IB2006/052612	31 July 2006 (31.07.2006)	31 July 2005 (31.07.2005)

Applicant
DISC-O-TECH MEDICAL TECHNOLOGIES, LTD. et al

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

The International Bureau of WIPO
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PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference 110/05400	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/IB2006/052612	International filing date *(day/month/year)* 31 July 2006 (31.07.2006)	Priority date *(day/month/year)* 31 July 2005 (31.07.2005)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant DISC-O-TECH MEDICAL TECHNOLOGIES, LTD.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 12 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☒	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☒	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 05 February 2008 (05.02.2008)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Cecile Chatel e-mail: pt13.pct@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IB2006/052612	31.07.2006	31.07.2005

International Patent Classification (IPC) or both national classification and IPC
INV. A61L24/06 A61L24/00

Applicant
DISC-O-TECH MEDICAL TECHNOLOGIES, LTD.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	see form PCT/ISA/210	FISCHER, J Telephone No. +31 70 340-2440

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IB2006/052612

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ on paper

   ☐ in electronic form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in electronic form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. II Priority

1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43*bis*.1 and 64.1) is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 24,26-28

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

☒ no international search report has been established for the whole application or for said claims Nos. 24,26-28

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has, within the applicable time limit:

   ☐ paid additional fees

   ☐ paid additional fees under protest and, where applicable, the protest fee

   ☐ paid additional fees under protest but the applicable protest fee was not paid

   ☒ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

   see separate sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-23

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	6-17,25
	No:	Claims	1-5,18-23
Inventive step (IS)	Yes:	Claims	6-17,25
	No:	Claims	1-5,18-23
Industrial applicability (IA)	Yes:	Claims	1-23,25
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item IV.

The separate inventions/groups of inventions are:

1-23,25
A bone cement comprising an acrylic polymer mixture, the cement characterized in that it achieves a viscosity of at least 500 Pascal-second within 180 seconds following initiation of mixing of a monomer component and a polymer component and characterized by sufficient biocompatibility to permit in-vivo use.

24
A bone cement comprising: a polymer component and a monomer component wherein contacting the polymer component and the monomer component produces a mixture which attains a viscosity greater than 200 Pascal-second within 1 minute from onset of mixing and remains below 2000 Pascal-second until at least 6 minutes from onset of mixing.

26-27
A particulate mixture formulated for preparation of a bone cement, the mixture comprising:
(a) 60 to 80% polymer beads comprising a main sub-population characterized by an MW of 150,000 Dalton to 300,000 Dalton and a high molecular weight sub-population characterized by an MW of 3,000,000 Dalton to 4,000,000 Dalton; and
(b) 20 to 40% of a material which is non-transparent with respect to X-ray.

28
A method of making a polymeric bone cement, the method comprising:
(a) defining a viscosity profile including a rapid transition to a working window characterized by a high viscosity;
(b) selecting a polymer component and a monomer component to produce a cement conforming to the viscosity profile; and
© mixing the polymer component and a monomer component to produce a cement which conforms to the viscosity profile.

They are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons:

The problem to solve by the present application is to manufacture an alternative bone cement composition characterized by a rapid transition from separate liquid monomer and powdered polymer components to a single phase characterized by a high viscosity when the components are mixed together.

The first proposed solution is a bone cement comprising an acrylic polymer mixture, the cement characterized in that it achieves a viscosity of at least 500 Pascal-second within 180 seconds following initiation of mixing of a monomer component and a polymer component and characterized by sufficient biocompatibility to permit in-vivo use.

A second proposed solution is a bone cement comprising a polymer (not only acrylic) component and a monomer component wherein contacting the polymer component and the monomer component produces a mixture which attains a high viscosity.

A third proposed solution is a particulate mixture formulated for preparation of a bone cement, the mixture comprising (a) 60 to 80% polymer (not only acrylic) beads comprising a main sub-population characterized by an MW of 150,000 Dalton to 300,000 Dalton and a high molecular weight sub-population characterized by an MW of 3,000,000 Dalton to 4,000,000 Dalton; and (b) 20 to 40% of a material which is non-transparent with respect to X-ray.

The method of making a polymeric bone cement composition is defined by mixing a selected polymer and a monomer to produce a cement which conforms to the desired viscosity profile.

The idea to use a bone cement comprising an acrylic polymer mixture comprising an acrylic polymer an a monomer and characterized by a high viscosity when the components are mixed together with substantially no intervening liquid phase is already known (see for example D1 -D7), and cannot serve as a single general inventive concept.

In the present application no further technical feature(s) can be distinguished that can be

regarded as a special technical feature involved in the technical relationship among the different inventions. Consequently, the present application lacks unity of invention, and the different solutions not belonging to a common inventive concept are identified as the different subjects listed in the communication pursuant to Article 17(3)(a)PCT. Each of the inventions listed is a distinct invention, characterised by its own special technical feature, defining the contribution which each of the claimed inventions, considered as a whole, makes over the prior art, i.e. the specific structural features of the individual groups of compounds.

Only the first subject was searched partially (see Point III).

The attention of the Applicant is drawn to the fact that further objections as to lack of unity of the inventions may be raised if the Applicant wishes to have an International Search Report for the other groups of inventions.

Re Item V.

1 Reference is made to the following documents:

D1 : LEWIS GLADIUS: "Properties of acrylic bone cement: State of the art review" JOURNAL OF BIOMEDICAL MATERIALS RESEARCH, vol. 38, no. 2, 1997, pages 155-182, XP002432739 ISSN: 0021-9304

D2 : LEWIS GLADIUS: "Toward standardization of methods of determination of fracture properties of acrylic bone cement and statistical analysis of test results" JOURNAL OF BIOMEDICAL MATERIALS RESEARCH, vol. 53, no. 6, 2000, pages 748-768, XP002432740 ISSN: 0021-9304

D3 : WO 2004/019810 A (BIOMET INC [US]; SMITH DANIEL B [US]; EPPLEY BARRY L [US]) 11 March 2004 (2004-03-11)

D4 : WO 99/18894 A1 (PARALLAX MEDICAL INC [US]; PREISSMAN HOWARD [US]) 22 April 1999 (1999-04-22)

D5 : FR 2 638 972 A1 (OSTEAL MEDICAL LABORATOIRES [FR]) 18 May 1990 (1990-05-18)
D6 : WO 2004/071543 A (SYNTHES AG [CH]; SYNTHES USA [US]; BISIG ADRIAN [CH]; BOHNER MARC [CH]) 26 August 2004 (2004-08-26)
D7 : EP 0 177 781 A1 (DRAENERT KLAUS) 16 April 1986 (1986-04-16)

2. Novelty

Document D1 discloses acrylic bone cement compositions presenting viscosity between 6 and 7800 Pascal-second within 180 seconds (table II; page 158, paragraph Viscosity). The subject-matter of D1 destroys the novelty of claims 1-5,18-23.

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-5,18-23 is not new in the sense of Article 33(2) PCT.

3. Inventive step

The problem to solve by the present application is to manufacture an alternative bone cement composition characterized by a rapid transition from separate liquid monomer and powdered polymer components to a single phase characterized by a high viscosity when the components are mixed together.

The proposed solution is a bone cement comprising an acrylic polymer mixture, the cement characterized in that it achieves a viscosity of at least 500 Pascal-second within 180 seconds following initiation of mixing of a monomer component and a polymer component and characterized by sufficient biocompatibility to permit in-vivo use.

Document D1, which is considered as closest prior art, discloses acrylic bone cement compositions presenting viscosity between 6 and 7800 Pascal-second within 180 seconds.

The difference between the claimed invention and the teaching of D1 appears to be a bone cement wherein the acrylic polymer is provided as a population of beads divided into

at least two sub-populations, each sub-population is characterized by an average molecular weight.

The objective problem to be solved by the present application in view of the teaching of D1, consists thus, in formulating an alternative acrylic bone cement characterized in that it achieves a viscosity of at least 500 Pascal-second within 180 seconds and comprising an acrylic polymer provided as a population of beads divided into at least two sub-populations, each sub-population is characterized by an average molecular weight.

No document of the cited prior art suggest such a specific acrylic bone cement composition.

Claims 6-17,25 are thus considered as involving an inventive step (Article 3383) PCT).

3. Industrial applicability

The subject-matter of claims 1-23,25 is considered industrially applicable, therefore claims 1-23,25 do meet the requirement of Article 33(4) PCT.

Re Item VIII
Certain observations on the international application

The term "monomer component" used in claim 1 is vague and unclear and leaves the reader in doubt as to the meaning of the technical features to which it refers, thereby rendering the definition of the subject-matter of said claim unclear.

Present claims 1-23,25 relates to a product defined (inter alia) by reference to the following unusual "viscosity" parameter.
The use of this unusual parameter, together with the wording "monomer compound" in the present context is considered to lead to a lack of clarity because the claims do not clearly identify the products encompassed by it as the parameters cannot be clearly and reliably

determined by indications in the description or by objective procedures which are usual in the art. This makes it impossible to compare the claims to the prior art. As a result, the application does not comply with the requirement of clarity under Article 6 PCT.

The lack of clarity is to such an extent, that the search was performed taking into consideration the non-compliance in determining the extent of the search of claims 1-23,25.

The search of claims 1-23,25 was restricted to the examples clearly defined in, and supported and disclosed by the description.

Should the applicant pay for additional search(es), the attention of the applicant is drawn to the fact that the wording of claims 24,26-28 is vague and unclear and leaves the reader in doubt as to the meaning of the technical features to which it refers, thereby rendering the definition of the subject-matter of said claim unclear.